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**Critical
Device
Corporation**

K 964989

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510(k) Summary

1. **Submitter:** **Critical Device Corporation**
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2. **Contact:** **Dan Hyun, President**
Critical Device Corporation
3. **Date prepared:** **December 10, 1996**
4. **Device trade name:** **CDC Vial and Bag Access Pins**

Model numbers:

CDC-P-1	1½" spike with female luer lock and 0.45 micron filtered vent
CDC-P-2	1½" spike with female luer lock, two-way check valve, and 0.45 micron filtered vent
CDC-P-3	2½" spike with female luer lock and 0.45 micron filtered vent
CDC-P-4	2½" spike with female luer lock, two-way check valve, and 0.45 micron filtered vent
CDC-P-5	2½" spike with extension line, female luer lock, and 0.45 micron filtered vent

Common name: **Intravenous (IV) Sets Accessory**
5. **Predicate device:** **Needle-Free Dispensing Pin, Burrion Medical Inc.**

CDC catalog number	corresponding BMI product number
CDC-P-1	DP -1000
CDC-P-2	DP -1500
CDC-P-3	DP -2001
CDC-P-4	DP -2500
CDC-P-5	DPL-2500
6. **Description:** **The CDC Vial and Bag Access Pin are adapters which pierce a rubber stoppered drug vial and/or bag and allows access to the contents. The CDC Vial and Bag Access Pins will be available with and without a 2-way luer activated check valve or with an extension line. The luer activated check valve or**

extension line is used to prevent loss of medication during aspiration or injection from inverted vials or bags. The 0.45 micron air vent is used to eliminate air and particulates in the vial or bag contents during aspiration. The CDC Vial and Bag Access Pin are provided sterile and non-pyrogenic in sealed single unit pouches.

7. Intended Use:

- a. For aspiration or injection of medical from inverted multidose vials and bags
- b. For use as part of a program to reduce the occurrence of needle stick injuries and the associated transmission of blood borne pathogens such as HIV and HBV.
- c. For use up to 24 hours, or in accordance with current guidelines of IV therapy.
- d. For use with standard luer taper connections.
- e. For single patient use.

8. Technological Comparison to predicate device:

The CDC Vial and Bag Access Pin design has essentially the same component materials and material source as the predicate Burron Medical Dispensing Pin. The non-shared assembly process and components of the protective end caps, tubing, and packaging are all currently qualified for product of other Critical Device Corporation product.

9. Nonclinical test summary:

Biocompatibility testing demonstrated compatibility with guidance standards except a statistically significant C3a compared to the untreated plasma control, though well below the activation of the positive control. The observed level of C3a is considered typical of this type of device (IV sets). There was however no statistical difference of C3a when evaluated against a similar marketed IV set.

10. Conclusion:

The CDC Vial and Bag Access Pins have demonstrated safety and effectiveness and are substantially equivalent to the legally marketed predicate device.